

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference PCT002SS	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/IN 2003/000400	International filing date (<i>day/month/year</i>) 26 December 2003 (26.12.2003)	(Earliest) Priority Date (<i>day/month/year</i>)
Applicant ALL INDIA INSTITUTE OF MEDICAL SCIENCES		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☒ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (See Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.: _____

☐ as suggested by the applicant.

☒ None of the figures.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN 2003/000400

CLASSIFICATION OF SUBJECT MATTER

IPC⁷: C07K 14/44, C12Q 1/68, G01N 33/569

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC⁷: C07K, C12Q, G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, EPODOC, Pubmed, Swiss-Prot, Entrez Protein, Entrez Nucleotide

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 1994 016331 (Jasys Corporation) 21 July 1994 (21.07.1994) <i>the whole document</i>	1-36
A	Burns JM Jr, et al. "Molecular characterization of a kinesin-related antigen of Leishmania chagasi that detects specific antibody in African and American visceral leishmaniasis." Proc Natl Acad Sci U S A. 1993, Vol. 90, No. 2, Pages 775-9. <i>the whole document</i>	1-36
A	Kumar R, et al. "Enzyme-linked immunosorbent assay for recombinant K39 antigen in diagnosis and prognosis of Indian visceral leishmaniasis." Clin Diagn Lab Immunol. 2001, Vol. 8, No. 6, Pages 1220-4. <i>the whole document</i>	1-36

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

„A“ document defining the general state of the art which is not considered to be of particular relevance

„E“ earlier application or patent but published on or after the international filing date

„L“ document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

„O“ document referring to an oral disclosure, use, exhibition or other means

„P“ document published prior to the international filing date but later than the priority date claimed

„T“ later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

„X“ document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

„Y“ document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

„&“ document member of the same patent family

Date of the actual completion of the international search

27 August 2004 (27.08.2004)

Date of mailing of the international search report

3 September 2004 (03.09.2004)

Name and mailing address of the ISA/AT

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/IN 2003/000400

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	Singh S, et al. "Diagnostic and prognostic value of K39 recombinant antigen in Indian leishmaniasis." J Parasitol. 1995, Vol. 81, No. 6, Pages 1000-3. <i>the whole document</i>	1-36
A	Braz RF, et al. "The sensitivity and specificity of Leishmania chagasi recombinant K39 antigen in the diagnosis of American visceral leishmaniasis and in differentiating active from subclinical infection." Am J Trop Med Hyg. 2002, Vol. 67, No. 4, Pages 344-8. <i>the whole document</i>	1-36
A	Singh S, et al. "Predicting kala-azar disease manifestations in asymptomatic patients with latent Leishmania donovani infection by detection of antibody against recombinant K39 antigen." Clin Diagn Lab Immunol. 2002, Vol. 9, No. 3, Pages 568-72. <i>the whole document</i>	1-36
A	Badaro R, et al. "rK39: a cloned antigen of Leishmania chagasi that predicts active visceral leishmaniasis." J Infect Dis. 1996, Vol. 173, No. 3, Pages 758-61. <i>the whole document</i>	1-36
A	Qu JQ, et al. "Serodiagnosis of Asian leishmaniasis with a recombinant antigen from the repetitive domain of a Leishmania kinesin." Trans R Soc Trop Med Hyg. 1994, Vol. 88, No. 5, Pages 543-5. <i>the whole document</i>	1-36

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/IN 03/00400-0

Patent document cited
in search report

Publication
date

Patent family
member(s)

Publication
date

A

none

Supplemental sheet

Restrictions of the search

-Claim 1 refers to a polypeptide, "wherein said polypeptide contains one or more repeat region(s) of 39 amino acids". Due to this broad and vague definition, only sequences according to Seq ID 5 and Seq ID 6 were included in the search.

- Claim 3 refers to "the polypeptides as claimed in claim 1, isolated from Indian strains of *Leishmania donovani*". Due to this broad and vague definition, only the strains disclosed in the application were included in the search, namely strains MHOM/IN/DD8 and MHOM/IN/KE16/1998.

-The "diagnostic kit for detecting leishmanial antigen comprising antibody bound to a solid support" as claimed in Claim 32 does not define the nature of the antibody used and was therefore restricted to antibodies according to claim 22 and a method according to claim 24.